PHARMACEUTICAL
QUALITY ASSURANCE

(As per PCI Syllabus BP 606T)

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PREFACE

Ensuring that pharmaceutical industry products and services fulfil the necessary quality standards is known as pharmaceutical quality assurance. By spotting and stopping flaws early on, it aims to build and maintain consumer confidence in the product. Within the pharmaceutical sector, quality assurance is a continuous process based on a detailed analysis of the needs and expectations of the customer. Different strategies can be used to assist with this process, but it's crucial to minimise extra costs for the business. Furthermore, pharmaceutical quality assurance's main goal is to reduce costs by upholding industry norms and pertinent regulations while maintaining high standards of quality.

The current **Pharmaceutical Quality Assurance** book was written in accordance with the Pharmacy Council of India's (PCI) revised B. Pharmacy syllabus. This book's comprehensive coverage encompasses the broader facets of pharmaceutical quality assurance needed by postgraduates, undergrads, industry professionals, researchers, and students getting ready for different competitive exams. This book stands out for being written in an understandable, straightforward, and clear style.

Links to websites and recommended reading are provided to assist readers in staying up to date on the most recent advancements in the field of pharmaceutical quality assurance. Introduction, background, objectives, principles, elements, description, organisation, concepts, and documentation have all been thoroughly divided into each chapter. According to the most recent revisions, the book has been written with graduate and postgraduate students' needs, teachers' needs, and research scientists' needs in mind.

Abbreviations

Absorption, Distribution, Metabolism, and Elimination (ADME)
Acceptable Daily Intake (ADI)
Asia Pacific Laboratory Accreditation Cooperation (APLAC)
Association of Official Analytical Chemists (AOAC)
Best Management Practices (BMPs)
Bovine Spongiform Encephalopathy (BSE)
British Pharmacopoeia (BP)
Clean in Place (CIP)
Collaborative International Pesticide Analytical Council (CIPAC)
Company-Wide Quality Control (CWQC)
Consumer Product Safety Act (CPSA)
Critical Process Parameters (CPPs)
Critical Quality Attributes (CQAs)
Crucial Material Attributes (CMAs)
Define, Measure, Analyze, Improve, Control (DMAIC)
Design of Experiments (DoE)
Design Qualification (DQ),
Effluent Treatment Plant (ETP)
Electronic Standards for the Transfer of Regulatory Information (ESTRI)
Endocrine Disrupting Chemicals (EDCs)
Engage in Quality Assessment Schemes Externally (EQAS)
Expert Working Group's (EWG)
Factory Acceptance Testing (FAT)
Food and Drug Administration (FDA)
Good Laboratory Practices (GLP)
Good Manufacturing Practices (GMP)
Indian Institute of Statistics (ISI)
Installation Qualification (IQ)
Internal Quality Control (IQC)
International Program on Chemical Safety (IPCS)
Limit Of Detection (LOD)
Limit Of Quantitation (LOQ)
Low Density Polyethylene (LDPE)
National Accreditation Board for Testing and Calibration Laboratories (NABL)
National Institute of Standards and Technology (NIST)
Operational Qualification (OQ)
Organizations for Economic Co-operation and Development (OECD)

Performance Qualification (PQ)
Permitted Daily Exposure (PDE)
Pharmaceutical Quality System (PQS)
Pharmaceuticals and Personal Care Products (PPCP)
Plan-Do-Check-Act (PDCA)
Process Analytical Technology (PAT)
Process Validation (PV)
Product Quality Review (PQR)
Quality Assurance" (QA)
Quality Attributes (CQAs)
Quality by Design (QBD)
Quality Control (QC)
Quality Management Philosophy (QMP)
Quality Management System (QMS)
Quality Target Product Profile (QTPP)
Quality, Safety, Efficacy, Multidisciplinary (QSEM)
Risk Assessment (RA)
Site Acceptance Testing (SAT)
Software Performance Engineering (SPE)
Standard Operating Procedures (SOPs)
Statistical Process Control (SPC)
Statistical Quality Control (SQC)
System Suitability Test (SST)
Tolerable Daily Intake (TDI)
Total Quality Management (TQM)
Toyota Production System (TPS)
United States Pharmacopoeia (USP)
User Criteria (URS)
User Requirements (URS)
Validation Master Plan (VMP)
World Health Organization (WHO)

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